**ORAL ARGUMENT SCHEDULED FOR DECEMBER 15, 2017**
**No. 17-5006**

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**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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**BILLINGS CLINIC, *et al.*,**
***Plaintiffs-Appellants,***

**v.**

**ERIC D. HARGAN, Acting Secretary,**
**Department of Health and Human Services,**
***Defendant-Appellee.***

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*On Appeal from the United States District Court*
*for the District of Columbia*
*Civil Action No. 1:13-CV-00643-RMC*

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# FINAL BRIEF FOR THE APPELLANTS

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Appellants, by and through their undersigned counsel, hereby certify the following as to Parties, Rulings and Related Cases:

### A. Parties And Amici

#### 1. Appellants

Appellants, plaintiffs below, are hospitals that participated in the Medicare program during all times relevant to this action. Attachment A shows all parent companies and any publicly held company that has a 10 percent or greater ownership interest in Appellants.

#### 2. Appellee

Appellee, defendant below, is the Secretary of the United States Department of Health and Human Services.

#### 3. Intervenors and Amici Curiae

There are no intervenors or amici curiae in this action and there also were none in the District Court.

### B. Rulings Under Review

Appellants seek review of the following rulings issued by the United States District of Columbia (Rosemary M. Collyer):

| Document Name | Date | JA No. | Official Citation |
|---|---|---|---|
| Memorandum Opinion | 6/11/2015 | 127 | 109 F. Supp. 3d 40 (D.D.C.) |
| Order | 6/11/2015 | 129 | N/A |
| Minute Order | 8/18/2015 | 182 | N/A |
| Opinion | 9/7/2016 | 252 | 206 F. Supp. 3d 307 (D.D.C. 2016) |
| Order | 9/7/2016 | 298 | N/A |
| Order | 11/10/16 | 300 | N/A |

### C. Related Cases

This case was not previously before this Court or any other court. Appellants are unaware of "any other related case," as defined by Circuit Rule 28(a)(1)(C). However, *Banner Health, et al v. Price*, Case No. 16-5129 (D.C. Cir.) ("*Banner Health*"), *University of Colorado Health At Memorial Health, et al v. Burwell*, Case No. 14-cv-01220-RC (D.D.C.), *Charleston Area Medical Center et al v. Burwell*, Case No. 15-cv-02031-JEB (D.D.C.), and *West Virginia University Hospital v. Hargan*, No. 1:17-cv-1573 (D.D.C.), include, among other issues,

issues similar to issues presented by this action, with the same defendant and some overlapping plaintiffs.

# ATTACHMENT A

# Corporate Disclosure Statement

| Hospital - Appellant | Parent(s) | Publicly held company that has a 10% or greater ownership interest in the entity |
|---|---|---|
| ALLINA HEALTH f/b/o Abbott-Northwestern | Allina Health | None |
| ALLINA HEALTH f/b/o Buffalo Hospital | Allina Health | None |
| ALLINA HEALTH f/b/o Cambridge Medical Center | Allina Health | None |
| ALLINA HEALTH f/b/o United Hospital | Allina Health | None |
| ALLINA HEALTH f/b/o Unity Hospital | Allina Health | None |
| ALLINA HEALTH f/b/o Mercy Hospital | Allina Health | None |
| ALLINA HEALTH f/b/o Owatonna Hospital | Allina Health | None |
| ALLINA HEALTH f/b/o St. Francis Regional Medical Center | Allina Health | None |
| BANNER HEALTH f/b/o Banner Good Samaritan Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o Banner Thunderbird Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o Banner Desert Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o Banner Boswell Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o Banner Del E. Webb Medical Center | Banner Health | None |

| Hospital - Appellant | Parent(s) | Publicly held company that has a 10% or greater ownership interest in the entity |
|---|---|---|
| BANNER HEALTH f/b/o Banner Baywood Heart Hospital | Banner Health | None |
| BANNER HEALTH f/b/o Banner Baywood Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o Estrella Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o McKee Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o North Colorado Medical Center | Banner Health | None |
| BANNER HEALTH f/b/o Banner Gateway Medical Center | Banner Health | None |
| HALIFAX COMMUNITY HEALTH SYSTEM, a/k/a Halifax Medical Center | Halifax Community Health System | None |
| SARASOTA MEMORIAL HOSPITAL | None | None |
| LEE MEMORIAL HEALTH SYSTEM f/b/o Lee Memorial Hospital | Lee Memorial Health System | None |
| LEE MEMORIAL HEALTH SYSTEM f/b/o Cape Coral Hospital | Lee Memorial Health System | None |
| LEE MEMORIAL HEALTH SYSTEM f/b/o Gulf Coast Medical Center | Lee Memorial Health System | None |

| Hospital - Appellant | Parent(s) | Publicly held company that has a 10% or greater ownership interest in the entity |
|---|---|---|
| BILLINGS CLINIC | None | None |
| CHARLESTON AREA MEDICAL CENTER | None | None |
| GOOD SAMARITAN HOSPITAL | None | None |
| VALLEY VIEW HOSPITAL | None | None |
| WEST VIRGINIA UNIVERSITY HOSPITALS | None | None |
| UNIVERSITY OF COLORADO HEALTH AT MEMORIAL HEALTH f/k/a Memorial Hospital of Colorado Springs | None | None |
| DENVER HEALTH MEDICAL CENTER | None | None |
| BOULDER COMMUNITY HOSPITAL | None | None |
| PARKVIEW MEDICAL CENTER | None | None |

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# TABLE OF AUTHORITIES

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## Cases



Authorities upon which we chiefly rely are marked with asterisks.

**Statutes**



**Other Authorities**

## GLOSSARY OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| APA | Administrative Procedure Act |
| AR | Administrative Record |
| Charge Ratio | Cost-to-Charge Ratio |
| DRG | Diagnosis Related Groups |
| FY | Federal Fiscal Year (October 1 – September 30) |
| IPPS | Inpatient Prospective Payment System |
| MedPAR File | Medicare Provider Analysis and Review File |
| HHS | Secretary of the United States Department of Health & Human Services |

## I. INTRODUCTION

Appellants, 33 non-profit acute care hospitals (the "Hospitals"), were injured by and challenge the invalid interpretation and application by the appellee Secretary of Health and Human Services ("HHS") of the outlier payment provisions under the Medicare Act. Through a series of invalid rules governing outlier payments during federal fiscal years 2008 through 2011, as well as the 2003 amendment to the outlier payment regulations, HHS harmed the very hospitals that Congress intended to protect with the outlier program.

## II. JURISDICTIONAL STATEMENT

The Hospitals brought this action in the district court pursuant to 42 U.S.C. § 1395oo(f)(1) for expedited judicial review of HHS's determinations of the amount of Medicare outlier payments, under 42 U.S.C. § 1395ww(d), for hospital fiscal years 2008 through 2011. The district court granted summary judgment in favor of HHS, disposing of all claims, in a memorandum opinion and order on September 7, 2016. Thereafter, on November 10, 2016, the district court denied the Hospitals' Rule 59(e) motion and the Hospitals timely appealed on January 4, 2017. This Court has jurisdiction under 28 U.S.C. § 1291.

## III. STATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Whether HHS arbitrarily and capriciously failed to consider its lengthy history of repeated substantial underpayments and to adjust its model

accordingly when determining whether the 2008-2011 thresholds were likely to produce payments at HHS's 5.1% target.

2. Whether, in each of its 2008-2011 rulemakings, HHS arbitrarily and capriciously persisted in forecasting the decline in charge ratios by means of a complex model that both conflicted with the actual available record rate of decline and repeatedly produced erroneous forecasts.

3. Whether HHS arbitrarily and capriciously failed to account for the impact of reconciliation (of overpayments) when setting the 2008-2011 thresholds.

4. Whether HHS's 2003 amendment to the outlier regulations violated notice and comment requirements under 5 U.S.C. § 553.

## IV. STATUTES AND REGULATIONS INVOLVED

Relevant statutes and regulations are set forth in the Addendum.

## V. STATEMENT OF THE CASE

### A. Factual Background

#### 1. Congress enacted the outlier statute to provide incentive and compensation for the treatment of extraordinarily sick Medicare patients

Medicare's Inpatient Prospective Payment System (IPPS) generally pays hospitals at fixed rates based on the average cost of treatment for the "diagnosis related group" (DRG) assigned to a case. 42 U.S.C. § 1395ww(d). However,

because hospitals "inevitably care for some patients whose hospitalization [is] extraordinarily costly" Congress enacted the outlier program to "insulate hospitals from bearing a disproportionate share of these atypical costs." *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1009 (D.C. Cir. 1999). Outlier payments also promote access to care by "alleviat[ing] any financial disincentive hospitals may" have to treat extraordinarily sick patients. **JA**327.

Under the outlier provisions, 42 U.S.C. § 1395ww(d)(3) & (5):

1. HHS makes outlier payments "in any case where charges, adjusted to cost, exceed … the sum of [the ordinary case payments] … plus a fixed dollar amount determined by [HHS]." 42 U.S.C. § 1395ww(d)(5)(A)(ii).[1] HHS sets that "fixed dollar amount" (the threshold) in its annual IPPS rulemakings.

2. Outlier payments "shall … approximate the marginal cost of care beyond the cutoff point," which is the sum of the threshold and the ordinary case payments. 42 U.S.C. § 1395ww(d)(5)(A)(iii).

3. For a given fiscal year, "[t]he total amount of the additional payments made under this subparagraph ... may not be less than 5 percent nor more than 6 percent of the total payments" under the overall DRG prospective payment system for that year. 42 U.S.C. § 1395ww(d)(5)(A)(iv). HHS has long interpreted this

[1] Ordinary case payments include the payment rate for the applicable DRG and other supplemental payments not here at issue. *See Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 50 n.1 (D.C. Cir. 2015).

text—with this Court's acquiescence—to mean that HHS must set thresholds "which, when tested against historical data, will likely produce aggregate outlier payments totaling between five and six percent of projected or estimated DRG related payments." *Cnty. of L.A.*, 192 F.3d at 1013 (emphasis added). For every year since 1989, HHS has stated that its target is for outlier payments to total 5.1% of total projected DRG payments. *See, e.g.*, **JA**477.[2]

4. Hospitals self-fund the outlier program through a reduction in base Medicare payment rates in a percentage amount equal to the percentage of total outlier payments being targeted. 42 U.S.C. § 1395ww(d)(3)(B). For each of the years at issue, HHS reduced each hospital's ordinary case payments by 5.1% to fund anticipated outlier payments.

2. HHS's payment regulations set the rules for determining outlier payments, including directing that hospital charges per case be converted to cost using "charge ratios"

HHS's regulations dictate which individual inpatient cases qualify for outlier payments under the applicable threshold set annually by HHS. 42 C.F.R. §§ 412.80-86. Under the regulations, HHS computes the cost of any given inpatient case by multiplying the hospital's billed charges for the case by the hospital's

[2] Each of HHS's thresholds at issue governed outlier payments during the applicable federal fiscal year, which runs October 1 - September 30: *e.g.*, the 2008 threshold governed from October 1, 2007 – September 30, 2008. Herein, each threshold will be indicated by the fiscal year during which it governed.

overall "cost-to-charge ratio" (charge ratio). For each hospital, the charge ratio is determined by dividing (1) the hospital's total Medicare costs in a fiscal year (as determined from its annual cost report) by (2) its total Medicare charges for that same year. *See* 42 C.F.R. § 412.84(g)-(h) (2003). The charge ratio represents a hospital's "average markup," and is "key" because "outlier payments are available only 'where charges, adjusted to cost, exceed'" the sum of the threshold and ordinary case payments. *See Dist. Hosp. Partners*, 786 F.3d at 50 (citation omitted).

Before 2003, HHS's outlier regulations were vulnerable to manipulation, because HHS calculated outlier payments using charge ratios that were either 3-5 years old at the time of payment or that had been automatically reset to a much higher statewide average.[3] Despite warnings from commenters,[4] HHS adopted and then persisted in applying these vulnerable payment rules for many years.[5]

A small subset of hospitals took advantage of these vulnerabilities through a practice that HHS, after the fact, would call "turbo-charging." *See* **JA**321-23;

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[3] *See* 53 Fed. Reg. 38,476, 38,503 (Sept. 30, 1988); **JA**307; **JA**312; *see also* 42 C.F.R. §§ 412.84(g) (1997-2002).

[4] *See, e.g.*, 53 Fed. Reg. at 38,507 (1989); 59 Fed. Reg. 45,330, 45,407-08 (Sept. 1, 1994) (1995).

[5] Although this appeal involves payments made under HHS's 2008-2011 thresholds and 2003 amendments to the payment regulations, earlier regulatory background is relevant and instructive.

*see also Dist. Hosp. Partners*, 786 F.3d at 51. Turbo-chargers spiked their billed charges faster than their charge ratios would be adjusted, under the regulations, in order to generate grossly overstated costs and outlier payments. **JA**321. Consequently, from 1997-2003, HHS paid the turbo-chargers more than $9 billion in invalid outlier payments. For example, according to HHS, a group of only 123 turbo-chargers (2% of all Medicare hospitals) had received 21.7% of all outlier payments during the first quarter of 2003 alone. **JA**403.

Instead of fixing the payment mechanism, HHS tried to cut back the ballooning payments by ramping up the threshold almost 250%—from $9,700 in 1997 to $33,560 in 2003. **JA**321. Hyper-inflating the threshold did nothing to contain the invalid overpayments, because turbo-chargers could always just charge more. But these steep threshold increases meant that compliant hospitals received significant underpayments, because the inflated thresholds blocked or reduced their valid outlier claims. **JA**321; **JA**327.

In 2003, HHS finally acknowledged how its payment regulations had spawned turbo-charging, and HHS amended the regulations to curtail that practice. **JA**321. The revisions were meant to tie payments more closely to a hospital's actual contemporaneous costs for a case through requiring the use of more recent charge ratios and eliminating the use of higher statewide average charge ratios. A key feature was also a process for reconciling payments after the fact. HHS

recognized that some residual turbo-charging would still be possible despite the other changes. **JA**326. Therefore, HHS concluded it was also "necessary" to review the most extreme outlier payments, reconcile them based on updated charge ratios, and recoup the excess with interest. **JA**329**, JA**340.

The 2003 rulemaking also presented the opportunity to rethink the threshold-setting process that had gone so far astray. HHS drafted an Interim Final Rule which acknowledged that its analytical method, in the circumstances of turbo-charging, had produced thresholds that were too high. **JA**368-432. The draft Interim Final Rule also recognized that HHS needed to modify its threshold-setting methods to reflect the changes in the payment rules. For example, because the new payment mechanism would pay hospitals based on more recent charge ratios, the draft Interim Final Rule included a method for projecting charge ratios to update them to the coming year. The result of the various methodological changes would have been to immediately lower the 2003 threshold from $33,560 to $20,760 (*i.e.*, it was 60% too high). **JA**383-84, **JA**401-02, **JA**405-06. However, although the HHS Secretary had signed the draft Interim Final Rule and sent it to the Office of Management and Budget (OMB) for review, HHS ultimately never published the Interim Final Rule. HHS also did not notify the public about the analysis and calculations in the draft Interim Final Rule, even though HHS selected pieces of the analysis therein on which to rely in its

published rulemaking. *Compare* **JA**307-16, *with* **JA**401-06. In the end, HHS disregarded the problem of underpayments to compliant hospitals and left the threshold at the turbo-charged peak of $33,560.[6]

A month later, HHS announced that it would lower the 2004 threshold by only about 8%,[7] even though the threshold had been raised by more than 60% the prior year due almost entirely to turbo-charging. **JA**383. The primary reason this adjustment was so trivial was that HHS—despite professing it had eradicated turbo-charging's impact—continued to use historically turbo-charged data to set the threshold.[8] As a result, as HHS later estimated, the 2004 threshold produced actual outlier payments totaling only 3.52%, or almost $1.4 billion short of HHS's target. *See* 70 Fed. Reg. 47,278, 47,496 (Aug. 12, 2005).

HHS also insufficiently lowered the 2005 and 2006 thresholds (respectively, to $25,800 and $23,600),[9] due in part to HHS's repeated failure to account for

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[6] A challenge to the 2003 rulemaking is currently pending a decision by this Court in *Banner Health*.

[7] *See* 68 Fed. Reg. 45,346, 45,477 (Aug. 1, 2003) (2004 threshold).

[8] This Court remanded the 2004 rulemaking to HHS in *District Hospital Partners*, 786 F.3d at 57-60, stating that HHS's "promulgation of the 2004 outlier threshold violated the APA" because HHS had failed to address the distorting effects of the data from turbochargers. *Id.* at 58. The 2004 rulemaking was also remanded by the district court in *Banner Health*, and a challenge to same, including to the agency's explanation on remand, is awaiting this Court's decision.

[9] *See* 69 Fed. Reg. 48,916, 49,278 (Aug. 11, 2004) (2005 threshold) & 70 Fed. Reg. at 47,494 (2006 threshold).

significant aspects of the new payment regulations. First, though now calculated using more recent data, the charge ratios used to set the threshold still lagged significantly behind updated charge ratios that would be used to pay actual claims. Therefore, because of a steady record trend of decline, the updated payment charge ratios would be materially lower than those used to set the threshold.[10] Second, HHS anticipated that it would recoup some outlier payments that were the product of residual turbo-charging through its new reconciliation requirements. Thus, to avoid overestimating the coming year's costs and setting the threshold too high, HHS needed to account for the record trend of decline in charge ratios and to account for the impact of reconciliation. But HHS simply ignored comments urging it to address both of these issues, and the resulting 2005 and 2006 thresholds produced actual outlier payments totaling, respectively, only 3.96% and 4.65% of total DRG payments rather than HHS's 5.1% target—a combined shortfall of roughly another $1.5 billion. *See* 71 Fed. Reg. 47,870, 48,152 (Aug. 18, 2006); **JA**478.

In the 2007 rulemaking, HHS finally began to take account of declining charge ratios. 71 Fed. Reg. at 48,150. But rather than projecting charge ratios using the readily available actual record trend of decline, HHS chose to model a

[10] As noted, in the draft Interim Final Rule, HHS had applied an adjustment factor to project the charge ratios forward. *See* **JA**405.

token rate of decline that was only one-seventh as large as the record decline.[11] And, once again, HHS refused to account for the impact of reconciliation. 71 Fed. Reg. at 48,149. The ensuing threshold was predictably too high and, according to HHS's estimate, produced actual outlier payments at only approximately 4.64% of HHS's target. **JA**519. Consequently, HHS again underpaid its target, this time by approximately $400 million.

3. For each of the 2008-2011 thresholds at issue, HHS continued to apply its failed formula, each year yielding a threshold that was too high and that predictably perpetuated HHS's historical underpayments

When setting the 2008-2011 thresholds, HHS continued to use the flawed model that had caused substantial underpayment in 2007. Each year, the result was an excessive threshold that was not "likely" to produce total outlier payments reaching the 5.1% target of total DRG payments. In fact, by HHS's own estimates, total outlier payments were only 4.8% for 2008, only 4.7% for 2010, and only 4.8% for 2011. *See* **JA**576; 76 Fed. Reg. 51,476, 51,795-96 (Aug. 18, 2011); 77 Fed. Reg. 53,258, 53,697 (Aug. 31, 2012). Although HHS had preliminarily estimated that total 2009 outlier payments were at 5.3%, commenters later showed they had actually reached only 4.9%. *Compare* **JA**628, *with* **JA**595.

[11] 71 Fed. Reg. 23,996, 24,150 (Apr. 25, 2006) (proposed 2007 rulemaking) & 71 Fed. Reg. at 48,150 (final 2007 rulemaking) (together, finding that the most-recent one-year decline in the average charge ratio was 2%).

Consequently, over 2008-2011, HHS underpaid its 5.1% target by approximately $1.7 billion.

a. HHS's 2008 threshold

HHS proposed to set the 2008 threshold by reapplying the same methodology it had used for 2007—*viz.*, modeling a token trend of decline in charge ratios and declining to account for the portion of outlier payments that HHS would be recouping with interest through reconciliation. **JA**434-35. HHS proposed only a slight decrease to the threshold. **JA**475.

Commenters strenuously objected, noting HHS's history of failing to meet its 5.1% target, which, *inter alia*, "penalized large, non-profit urban safety-net hospitals." **JA**471. The Federation of American Hospitals identified, among other things, material flaws in HHS's modeled adjustment factor for charge-ratios and expressly proposed the alternative of using the actual historical record trend. **JA**446-47, **JA**460.[12]

However, HHS "did not budge," *Lee Mem'l Hosp. v. Burwell*, 206 F. Supp. 3d 307, 318 (D.D.C. 2016)(RMC), **JA**264 ("DE82"), and made none of the

[12] *See also* similar comments at **JA**438-40, **JA**441-42, **JA**447-48, **JA**460-61, **JA**463, **JA**468-69. Importantly, as the Federation noted, the data available at the time of the proposed rule would be updated prior to the final rule and would likely result in a further decrease in the threshold. **JA**447 n.5. In fact, multiple variables used in HHS's final rule decreased. *Compare* **JA**475, *with* **JA**476. This was true in each of the 2008-2011 rulemakings. *See* **JA**191 n.12.

suggested methodological improvements, **JA**476-77. HHS's final 2008 threshold of $22,635 produced, according to HHS's estimate, outlier payments totaling only 4.8% of total DRG payments. **JA**576.

b. HHS's 2009 threshold

The 2009 rulemaking was a virtual repeat of 2007 and 2008. HHS again proposed using the same deficient method first used in the 2007 final rule,[13] despite finding its past two thresholds had paid substantially below the 5.1% target. **JA**519. Commenters again noted the same flaws in HHS's methodology, and recommended the same measures to improve accuracy. **JA**499-500, **JA**492-94; **JA**500-01; **JA**503; **JA**506-07; **JA**509-11; **JA**513. And, once again, HHS "was implacable," **JA**265, making no improvements to its methodology, **JA**517-18.

HHS set the final 2009 threshold at $20,045. **JA**522.[14] Thus, HHS's 2009 threshold had finally reached the level at which the draft Interim Final Rule stated it should have been set six years earlier in 2003. Furthermore, as noted, commenters calculated that the 2009 threshold actually produced outlier payments

[13] **JA**484.

[14] HHS's final rule originally set the threshold at $20,185. **JA**517. However, HHS revised the final FLT to $20,045 in a supplemental notice. **JA**522.

totaling only 4.9% of total DRG payments. **JA**602. Thus even a 2009 threshold of $20,045 was too high.

c. HHS's 2010 threshold

The 2010 rulemaking was yet another repeat of 2007: HHS proposed using the same method that had failed multiple times;[15] commenters identified the same flaws in HHS's method and again suggested superior alternatives;[16] and HHS rejected all of these suggestions, making no improvements to its methodology.[17]

The only difference in 2010—and it is notable—was that HHS now rationalized raising the threshold based on its estimate that, for the first time in six years, its threshold for the prior year (2009) had produced total outlier payments above (and only slightly above) the 5.1% target. Commenters questioned the validity of HHS's preliminary estimate, believing it to have been overstated. **JA**536, 541.[18] HHS's final 2010 threshold of $23,140 again proved to be too high, with total outlier payments at only 4.7% of total DRG payments, approximately $350 million below HHS's target. 76 Fed. Reg. at 51,795-96.

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[15] **JA**526-28.

[16] **JA**545-47; **JA**531; **JA**532; **JA**538; **JA**550.

[17] **JA**574.

[18] Commenters continued to note differences between their actual data and HHS's modeled calculations of past outlier payments and requested that HHS "revisit its calculations and publish an explanation in the Preamble to the Final Rule to explain the discrepancies in 2008, and perhaps for prior years as well." **JA**541. *See* table *infra* at 25. In response, HHS offered no explanation. **JA**575-76.

d. HHS's 2011 threshold

HHS's 2011 threshold rulemaking followed the worn out path of the prior four rulemakings: HHS used the same failed methodology,[19] commenters urged the same improvements,[20] and HHS again rejected the improvements for the same reasons given in previous years.[21] Commenters also continued to note that they had calculated materially lower past outlier payments than those calculated by HHS, especially for 2009, the only year for which HHS's preliminary estimate suggested payments had been slightly above the 5.1% target. **JA**595.

HHS's 2011 threshold of $23,075, **JA**627, was again too high and produced outlier payments totaling only 4.8% of total DRG payments, or roughly $250 million short of HHS's target. 77 Fed. Reg. at 53,697.

## B. Procedural History

On September 7, 2016, the district court denied the Hospitals' motion for summary judgment and granted HHS's cross-motion to dismiss or, in the alternative, for summary judgment. *See* **JA**298. The Hospitals appeal this ruling.[22]

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[19] **JA**584.

[20] **JA**596-97, **JA**600; **JA**588-89; **JA**591; **JA**595; JA598; **JA**602; **JA**605-07; **JA**609; **JA**611; **JA**613; **JA**615; **JA**616; **JA**617; **JA**618; **JA**619; **JA**621.

[21] **JA**625-26.

[22] The Hospitals also timely moved to amend or alter the judgment, and the district court denied that motion on November 10, 2016. **JA**304.

## VI. SUMMARY OF THE ARGUMENT

HHS annually sets an outlier-payment threshold that it determines will "likely" result in outlier payments totaling 5.1% of HHS's total DRG payments. Such a determination must rest on a sound, rational forecast of what payments HHS will make given the chosen threshold. However, HHS's forecasting method was irrational during each of the 2008-2011 threshold determinations at issue.

HHS stated that its thresholds would likely result in outlier payments at 5.1% of total payments, but it lacked any real basis for making that prediction. From and after 2004, HHS's forecasting method regularly overestimated the amount of outlier payments, and that repeated error cast doubt on the soundness of HHS's predictions. Yet HHS did not question its method or investigate why it systematically produced overestimates, even though commenters offered explanations. If a model has produced the wrong answer multiple times in a row, it is arbitrary and capricious to assert that the same model, without adjustments or corrections, or even investigation of the errors, will "likely" be correct the next time.

HHS was indifferent to basic flaws in its methodology that contributed to its predictive errors. First, HHS forecasted charge ratios (a primary determinant of outlier payments) by fabricating a complex model that had little relationship with reality. The model repeatedly overestimated charge ratios by significant amounts,

in part because the model's important underlying assumptions were unjustified. HHS continued to use the model even though a simpler approach was readily available, repeatedly suggested by commenters, and similar to what HHS itself did to adjust another important factor (charges). HHS's continued adherence, without reasonable justification, to a model that demonstrably did not correspond to reality (*viz.*, the actual record data) was arbitrary and capricious.

Second, HHS did not account for the portion of payments it would claw back using the reconciliation process—payments that would reduce the total outlier payments each year. HHS had already said that reconciled payments should not count toward the statutory 5-6% target, but in the years at issue it simply refused to estimate what the volume of reconciled payments would be. Having omitted this important factor, HHS could not rationally predict what the total of outlier payments would "likely" be.

HHS could have avoided these errors, produced more reliable predictions, and thus set reasonable thresholds had it taken seriously the multiple comments each year suggesting alternative methods. Worse, HHS had itself already considered superior methods, as the analysis set forth in the 2003 draft Interim Final Rule demonstrates. In that 2003 rulemaking, which solved the longstanding problem of excessive claims by a few hospitals but did little to improve HHS's threshold-setting process, HHS cherry-picked that analysis and did not provide

public notice of the important aspects that ran contrary to its published position and would have helped compliant hospitals receive proper payments.

Each year, by paying less in total outlier payments than it had withheld from normal case payments, HHS removed hundreds of millions of dollars from the Medicare Program. That result was not what Congress intended when it established the outlier program for the purpose of protecting hospitals from extraordinarily costly cases.

## VII. ARGUMENT

### A. Standard of Review

This Court reviews a grant of summary judgment *de novo*. *Deppenbrook v. Pension Benefit Guar. Corp.*, 778 F.3d 166, 171 (D.C. Cir. 2015). Where the dispute involves the review of agency action, the Court "review[s] the administrative record" directly and "accord[s] no particular deference to the judgment of the District Court." *Id.* (internal quotation marks omitted). This Court will overturn summary judgment for the agency if the agency "violated the Administrative Procedure Act by taking action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* (quoting 5 U.S.C. § 706(2)).

### B. HHS Set The 2008-2011 Thresholds At Excessive Levels That Were Not Likely To Produce Total Outlier Payments At HHS's 5.1% Target

HHS must set the threshold at a level that will "likely" produce total outlier payments, during the coming year, at 5.1% of total estimated DRG payments. *See Cnty. of L.A.*, 192 F.3d at 1013. However, for each of the 2008-2011 thresholds at issue, HHS repeatedly used a process that produced actual total outlier payments well below HHS's target. HHS was indifferent to these underpayments, which were caused primarily by HHS's repeated failure to account rationally for two significant record facts: declining charge ratios; and outlier payments that would be recouped through reconciliation. These repeated flaws caused HHS to

overestimate total outlier payments in its projections and, thus, to set excessive thresholds that were not likely to produce payments at HHS's 5.1% target.

1. HHS was indifferent to its record of repeated underpayments and unreasonably refused to question the efficacy of its projection model

An agency must, of course, consider the prior results of predictive modeling to evaluate the model's efficacy. *See Am. Petroleum Inst. v. EPA*, 706 F.3d 474, 477 (D.C. Cir. 2013) ("considering whether to maintain a methodology necessarily invites reflection on the success of earlier applications"); *see also Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1053 (D.C. Cir. 2001) (remanding in part for failure to explain "disparity between EPA's growth projections and observed growth rate," stating that "[w]hile courts routinely defer to agency modeling of complex phenomena, model assumptions must have a 'rational relationship' to the real world" (citation omitted)). That obligation is particularly pertinent when making a reasonable prediction is the main task in a rulemaking—as it was in these rules, for which HHS had to determine that a given threshold would "likely" result in a certain amount of payments. During each rulemaking at issue, HHS noted whether total payments made under prior thresholds had actually reached its 5.1% target. Each time when total payments were well below the target—demonstrating that HHS's model was ineffective and required improvement—HHS was indifferent and made no modeling adjustments to lower the threshold. In contrast,

HHS consistently relied on any perceived overpayment to rationalize increasing the threshold. Exacerbating this problem, HHS also refused to confront evidence submitted by commenters that HHS's estimates of past payments were substantially overstated.

a. HHS ignored multiple years of underpayment but seized on one year's alleged slight overpayment to justify raising the threshold

HHS asserted to the district court that it "considers past outlier payments during each year's rulemaking, responds to comments regarding past payments, and, as it thinks appropriate, adjusts the model to set the next [threshold]." **JA**286. However, HHS did not treat historical overpayments and underpayments alike, and it offered no explanation for this difference in treatment. HHS's approach was analogous to the one-sided economic analysis—counting the benefits of a policy choice but not the costs—that the Court rejected in *Business Roundtable v. SEC*, 647 F.3d 1144, 1148-49 (D.C. Cir. 2011) (finding agency acted arbitrarily and capriciously where it "inconsistently and opportunistically framed the costs and benefits of the rule").[23]

HHS had historically reacted to overpayments by modifying its methodology in ways that increased the threshold. For example, from 1997-2003, HHS relied on

[23] The Hospitals made this argument in their summary judgment briefing, *see* **JA**192-95, but the district court overlooked it.

prior overpayments to justify increasing a factor used to estimate costs and, therefore, to increase the threshold. *See* 64 Fed. Reg. 41,490, 41,546 (July 30, 1990) ("[the cost inflation factor] reflects [HHS's] analysis … indicating that the percentage of actual outlier payments for FY 1998 is higher than [HHS] projected before the beginning of FY 1998, and that the percentage of actual outlier payments for FY 1999 will likely be higher than [HHS] projected before the beginning of FY 1999."); 65 Fed. Reg. 47,054, 47,113 (Aug. 1, 2000) (same); 66 Fed. Reg. 39,828, 39,941 (Aug. 1, 2001) (same). Similarly, for its 2010 rulemaking, HHS justified a proposed steep 21% increase in threshold based on its preliminary estimate that, for the first time in six years, it had overpaid in 2009. *See* **JA**573 ("we are currently projecting 5.4 percent of total IPPS payment will be paid as outlier in FY 2009 or 0.3 percentage points higher than the 5.1 percent originally estimated. If we do not increase the FY 2009 threshold in FY 2010, we would continue to make outlier payments in excess of the 5.1 percent target.").[24]

In contrast, HHS did not view its substantial estimated underpayments, in 2007, 2008, and 2010, as reasons to adjust its methodology so as to reduce the

[24] Although HHS estimated that 2009 outlier payments totaled 5.4%, commenters noted that HHS's preliminary estimates were typically overstated and "when final data are available" outlier payments for 2009 "will not have exceeded the 5.1% target." **JA**536. *See also infra* 25-26. Also, the estimated 5.4% fell squarely within the 5-6% statutory mandate and, thus, would hardly warrant a 21% increase in the threshold.

2008, 2009 and 2011 thresholds. Each time, HHS was, at best, indifferent to comments calling for HHS to improve its projection model. **JA**475-77 (declining to adopt commenters' suggestions to improve its projection methodology so as to avoid underpayments), **JA**516-19 (same), **JA**625-27 (same). HHS's indifference to past underpayments, while raising the threshold in response to past overpayments, was arbitrary and capricious. *See Cnty. of L.A.*, 192 F.3d at 1022 ("[A]gency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently." (citations omitted)).

The district court concluded in a footnote that HHS reasonably waited for several years of experience (in fact waited seven years, until 2014) before it decided to modify the methodology it had first developed for the 2007 rulemaking. **JA**282 n.15. But HHS never offered that reason in its rulemakings. Instead, when commenters pointed out the underpayments, HHS simply ignored the issue. For example, in the 2008 rulemaking, a commenter observed that 2007 payments were short by about $420 million, and the commenter suggested that shortfall should motivate several changes to the methodology. **JA**475-76.[25] HHS said nothing about the underpayment, and it reasserted the soundness of its method without even exploring why its prediction had been so far off. **JA**476.

[25] *But cf.* **JA**197 (HHS brief arguing that information about 2007 payments was not available until the 2009 rulemaking).

HHS has also argued that a predictive judgment does not become arbitrary and capricious simply because events develop differently from the prediction. **JA**185. The Hospitals recognize, of course, that prediction inherently involves some uncertainty. Nonetheless, HHS must have believed its predictive model produced reasonable forecasts of outlier payments; otherwise HHS could not have determined that outlier payments would "likely" be above the 5.0% statutory floor. Yet HHS's model overestimated outlier payments, by substantial amounts, year after year. HHS's misplaced confidence in the model, without any examination of why the model's output was consistently off-target, was arbitrary and capricious. *See Am. Petroleum Inst. v. EPA*, 706 F.3d at 477 (observing that "considering whether to maintain a methodology necessarily invites reflection on the success of earlier applications"); *see also Appalachian Power Co.*, 249 F.3d at 1053 (remanding in part for failure to explain disparity between projections and results).

b. HHS also overestimated its past payments, thus failing to consider by how much it had actually underpaid

HHS also arbitrarily and capriciously "failed to consider" evidence that the agency's process for calculating past outlier payments was itself faulty and grossly over-estimated prior total outlier payments. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). HHS had actual record data

demonstrating the aggregate amount of outlier payments made during prior years. **JA**478, **JA**519, **JA**575-76, **JA**628. However, HHS disregarded the actual data and, instead, decided to model the amount of past payments. And once again, HHS's model was off the mark, consistently overestimating total payments and, hence, understating the amount by which HHS had underpaid the hospitals. Consequently, HHS did not fully consider the enormity of its underpayments ($1.7 billion for the years at issue), which is "an important aspect of the problem" as to whether HHS's threshold methodology was sound. *State Farm*, 463 U.S. at 43.

It bears emphasis that evidence of the agency's underestimates of prior underpayments was in the record for each of the 2008-2011 rulemakings. For example, in the 2008 rulemaking, commenters stressed that HHS had underpaid its 5.1% target (and 5.0% statutory floor) for the past four years by over $3.5 billion. **JA**450. Similarly, in each of the 2009-2011 rulemakings, commenters presented detailed calculations (summing actual data) of HHS's underpayments in the prior years. *See, e.g.*, **JA**599 (table showing HHS had underpaid $1.7 billion over 2007-2010). The table below collects and reproduces data that commenters submitted showing that HHS consistently overestimated past outlier payments.

| FY | HHS's Estimate | Commenter Estimate | Estimated Shortfall Based on Commenter Estimate |
|---|---|---|---|
| 2004 | 3.52% | 3.40% | $1.40B |
| 2005 | 3.96% | 3.80% | $1.10B |
| 2006 | 4.65% | 4.40% | $649M |
| 2007 | 4.64% | 4.30% | $695M |
| 2008 | 4.80% | 4.57% | $467M |
| 2009 | 5.30% | 4.86% | $220M |
| 2010 | 4.70% | 4.39% | $624M |
| 2011 | 4.80% | 4.58% | $441M |

[26]

When confronted with concrete proof of its substantial underestimates of its underpayments, HHS neither disputed the proof nor explained why the commenters' detailed analysis (based on actual historical record data) might be in error. *Compare* **JA**461; **JA**495; **JA**501-02; **JA**549-50; **JA**607-08, *with* **JA**478; **JA**519; **JA**575-76; **JA**628. Instead, HHS just plowed forward uncritically assuming that its estimates were sound. HHS's estimate as to 2009 is especially troubling because, HHS relied on a preliminary estimate of an overpayment to raise the 2010 threshold, while commenters both noted this estimate was likely

[26] The above table with record citations was presented with the Hospitals' summary judgment motion. *See* **JA**192. HHS did not dispute the figures in the district court. **JA**202-04. The commenter's estimated underpayments for 2010 and 2011 in the table came from subsequent rulemakings and confirm the consistent size of HHS's underestimates. Further, the table's dollar figures on the estimated shortfalls are higher than the shortfalls in the Factual Background, *see supra* 9-14, which are based on HHS's own modeled estimated underpayments.

incorrect and later calculated an underpayment using the actual payment data. **JA**536; **JA**595. This was not reasoned decision making, as HHS's overestimates masked just how far the agency's modeling assumptions were divorced from "the real world." *Appalachian Power Co.*, 249 F.3d at 1053; *see also Gas Appliance Mfrs. Ass'n v. DOE*, 998 F.2d 1041, 1045-46 (D.C. Cir. 1993) ("the accuracy of any computer model hinges on whether the underlying assumptions reflect reality") (internal quotation marks omitted).

2. HHS unreasonably disregarded the actual record trend of decline in hospital charge ratios—a key variable used to project outlier payments—and instead modeled and applied a much smaller, demonstrably inaccurate trend

HHS sets the threshold at a level which, under HHS's models, produces total projected outlier payments at a 5.1% target.[27] To project the total outlier payments, HHS uses historical claims data, which it must bring current to the coming year by forecasting changes to the hospitals' charges for the claims and to the hospitals' charge ratios that will later be used to determine payments.[28] Such forecasting is

[27] *See, e.g.*, **JA**475 (2008) ("to calculate the proposed FY 2008 outlier threshold, we simulated payments by applying FY 2008 rates and policies using cases from the FY 2006 MedPAR files"); **JA**516 (same for 2009); **JA**571 (same for 2010); **JA**624 (same for 2011).

[28] *See, e.g.*, **JA**475-76 (2008). HHS's historical claims data file (known as the "MedPAR" file) was from two years prior to the year being modeled. **JA**475. HHS sourced the charge ratios from another database (the Provider Specific File), using data that was current as of six months before the upcoming year being modeled. *Id.*

necessary because the record showed that, for more than a decade, without interruption, charges had been increasing at a faster rate than costs and, consequently, that charge ratios had been decreasing.[29]

Prior to and for each of the 2008-2011 threshold rulemakings, HHS projected charges forward in time based on their actual historical rate of growth. This had the effect, all other things being equal, of increasing the threshold. HHS similarly could have projected the charge ratios forward using their actual historical rate of decline (thus decreasing the threshold). But rather than using this obvious and straightforward means, HHS used a fundamentally flawed model to forecast the average rate of change in charge ratios. HHS's model produced rates of change that were substantially different from anything seen in recent years. For example, in the 2008 rulemaking, HHS's model actually forecast that charge ratios would increase, notwithstanding that the actual record data again showed an uninterrupted continuing trend of substantial decrease.

HHS never even acknowledged, much less addressed, the fact that its modeled trend departed so significantly from the historical trend, despite comments repeatedly identifying the model's flaws. As a direct result, each year,

[29] More specifically, the charge ratios on file and used to project payments (projection ratios) would soon be outdated and replaced by, on average, one-year newer and lower charge ratios used to make actual payments during the coming year (payment ratios). *See* 71 Fed. Reg. at 48,150 (2007); *see also* **JA**475-76 (2008); **JA**516-17 (2009); **JA**572, **JA**574 (2010); **JA**624, **JA**626 (2011).

HHS persistently used overstated charge ratios to set the threshold. These overstated charge ratios yielded excessive thresholds that predictably paid hundreds of millions of dollars less in outlier payments than HHS had projected and had deducted from hospitals' regular payments. HHS's indifference to the fact that its method essentially "baked in" enormous underpayments was arbitrary and capricious.

a. HHS unreasonably used modeled rates of change, to charge ratios, without considering that the actual record data showed a much steeper and uninterrupted rate of decline

If HHS had lacked data on the rate of change in charge ratios, it might have made sense to construct a theoretical model of that rate of change. But the opposite was true. During its 2008-2011 rulemakings, HHS had at its fingertips recent actual record data showing an uninterrupted trend of substantial decline in charge ratios. Specifically, HHS computed and used the national average charge ratio for two other purposes in each of the same 2008-2011 rulemakings.[30] Moreover, in the 2008 and 2009 rulemakings, HHS cited the most recent statistics on the 1-year decline in the national average charge ratio. *See* **JA**477 (2008) (finding additional decrease of 1.5%); **JA**518 (2009) (finding additional decrease

[30] HHS calculated and used the national average charge ratio both to determine the level above which charge ratios would default to a statewide average and to calibrate the DRG weights. These facts, which HHS did not deny below, were supported by citations to the record. *See* **JA**208 n.8-9.

of 1.3%). Without explanation, however, HHS disregarded this robust data reflecting the actual record trend of decline and instead used an artificial rate of change, based on a complex model which was divorced from the actual rate of change.[31]

For 2008, HHS's model predicted that charge ratios would on average increase by 0.27%, when the most recent historical data showed an average decrease of 2.5%. HHS's artificial trend was not only counter to the record trend but also conflicted with the reason for adjusting charge ratios in the first place: *viz.*, they were declining. Indeed, the sole reason HHS used charge inflation to model upcoming costs was because HHS had repeatedly found that charges were increasing faster than costs.[32] The table below compares (a) the then most-recent actual historical rate of decline to (b) HHS's modeled rate of change. Repeatedly, HHS forecast rates of change that looked nothing like any rate seen in the many years leading up to or during 2008-2011.

[31] HHS's faulty adjustment-factor formula is described below in detail at 34-38.

[32] *See, e.g.*, 69 Fed. Reg. at 49,277 (2005), 70 Fed. Reg. at 47,495 (2006) (rejecting suggestion to stop using charge inflation to project costs).

**National Average Operating Charge Ratio**

| Year | Historical Impact File | Actual Record % Change | HHS's Modeled % Change |
|---|---|---|---|
| 2004 | 0.401 | | |
| 2005 | 0.385 | -4.01% | |
| 2006 | 0.365 | -5.34% | |
| 2007 | 0.352 | -3.39% | -0.27% |
| 2008 | 0.344 | -2.50% | +0.27% |
| 2009 | 0.334 | -2.78% | -0.68% |
| 2010 | 0.329 | -1.40% | -1.20% |
| 2011 | 0.322 | -2.35% | -0.90% |

[33]

It bears emphasis that the relevant data on the actual historical trend of decline in charge ratios was in the record for each of the 2008-2011 rules. For example, the 2008 rulemaking record showed that the most recent actual rate of decline was -2.5%, but HHS forecast an increase of +0.27%. For 2009, the record showed the most recent actual rate of decline was -2.78%, while HHS forecast a decline of only -0.68%. The 2010 and 2011 rulemaking records also reflected

[33] HHS did not dispute below the figures in this table, *see* **JA**197; **JA**212-13, which was compiled from data in the "Impact File" for each of HHS's 2004-2011 rulemakings. More specifically, each "Impact File" provides "the bases for HHS's determination of the fixed loss thresholds." *Lee Mem'l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 49 (D.D.C. 2015) (RMC); **JA**128 (quoting HHS's declarant). HHS's modeled rates of change for charge ratios and the Impact Files for the years here at issue are in the record (*see* **JA**476, **JA**482, **JA**517, **JA**523, **JA**574, **JA**581, **JA**627, **JA**630) and, along with those for 2004-2007, are also publicly available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html.

actual historical trends of decline that were materially larger than HHS's modeled rates of change those years.

Thus, the rates of change in charge ratios that HHS modeled and used deviated significantly from (indeed, were simply unrelated to) the real data in the record. Given those stark differences, HHS's uncritical use of the rates its model produced was, distinctly, arbitrary and capricious. "[A]gencies do *not* have free rein to use inaccurate data [and] … [i]f an agency fails to examine the relevant data—which examination could reveal, *inter alia*, that the figures being used are erroneous—it has failed to comply with the APA." *Dist. Hosp. Partners*, 786 F.3d at 56-57. "While courts routinely defer to agency modeling of complex phenomena, model assumptions must have a rational relationship to the real world." *Appalachian Power Co.*, 249 F.3d at 1053 (internal quotation marks omitted); *see also Cnty. of L.A.*, 192 F.3d at 1010, 1021-1023 (rejecting, as "counter to the evidence before the agency," HHS's explanation for using certain data, which "obviously did not reflect" HHS's expectations about the payment system). HHS's modeled forecasts of charge ratios bore no "rational relationship" with "the known behavior" of charge ratios, *Chem. Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1265 (D.C. Cir. 1994), and this Court should hold invalid the threshold determinations that depended on those forecasts. *See, e.g., Sorenson Commc'ns, Inc. v. FCC*, 755 F.3d 702, 709 (D.C. Cir. 2014) (setting aside rule where it "is not

only unsupported by the evidence, but contradicted by it"); *Gas Appliance Mfrs. Ass'n*, 998 F.2d at 1045-46 ("the accuracy of any computer model hinges on whether the underlying assumptions reflect reality") (internal quotation marks omitted).

Moreover, the simpler alternative of projecting the charge ratios based on the most-recent historical trend was clearly on the table. HHS both used this same basic method to project changes in charges and commenters repeatedly suggested that using the historical trend would yield more accurate projections and that HHS's method was faulty. *See, e.g.*, **JA**460; **JA**447.[34] However, HHS never actually explained in the rulemakings why it persisted with its attempt to model a trend that was already manifest in the record.

The only explanation HHS gave for using its complex model was that the model purportedly produced a "more accurate and stable" measure of "cost inflation." **JA**476.[35] But adjusting charge ratios using the historical trend of

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[34] In the district court, HHS had initially asserted that no one had come forward to suggest a reasonable alternative to HHS's model for adjusting charge ratios. **JA**188-89. However, HHS ultimately acknowledged that commenters had suggested using the historical data trend. *See* **JA**200 (discussing comment on this issue).

[35] HHS handled these comments quite cavalierly. In the 2008 rulemaking, dismissing a suggestion that it should forecast charge ratios the same way it forecast charges, HHS repeated the same explanation—word for word—that it had provided to totally different suggestions the year before. **JA**476 (2008); 71 Fed. Reg. at 48,151 (2007). This pattern was repeated during the 2009-2011

decline did not involve a measure of cost inflation and, instead, just measured the rate by which the national average charge ratio had declined. Further, and significantly, the rate of change in charge ratios that HHS's model forecasted was always substantially inaccurate as compared to the actual historical data. HHS did not address this point in any of the 2008-2011 rulemakings, which failures were also arbitrary and capricious. *See Bus. Roundtable*, 647 F.3d at 1151 (holding that the agency had "not sufficiently supported its conclusion" especially in light of the empirical evidence that plaintiffs brought to its attention); *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (agency's failure to respond meaningfully to objections renders a decision arbitrary and capricious); *Del. Dep't of Natural Res. & Envtl. Control v. EPA*, 785 F.3d 1, 14-16 (D.C. Cir. 2015) (holding that the EPA's "wan responses" to comments comprised a "refus[al] to engage with the commenters' . . . argument" and were, thus, insufficient as they did not allow the court to see why the EPA had reacted to the comments as it did).

Moreover, HHS did not explain why it treated charges and charge ratios differently—HHS did not compare the level of fluctuations in these two variables.

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rulemakings, *viz.*, (1) commenters repeatedly noted that HHS's modeled adjustment factor was inaccurate and recommended the obvious (and superior) alternative of using the actual record 1-year change in the national average charge ratio and (2) HHS repeatedly gave the same non-response, addressing instead different alternatives that had not been suggested since the 2007 threshold. **JA**492, **JA**517 (2009); **JA**537 (2010); **JA**597; **JA**625 (2011).

In fact, charges had historically fluctuated by about as much as charge ratios,[36] but those fluctuations did not deter HHS from using the simple historical data to forecast charge increases. None of these rulemakings explained why HHS treated charges and charge ratios differently; none even acknowledged the difference. That failure, too, is arbitrary and capricious. *Cnty. of L.A.*, 192 F.3d at 1022 ("agency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently").[37]

b. HHS's model was conceptually irrational and repeatedly produced grossly inaccurate modeled forecasts of charge ratios

As shown, HHS did not offer any sensible reason for using a complex model rather than the actual record historical data to forecast charge ratios. Moreover, HHS's model itself suffered from basic methodological flaws. Commenters pointed out these problems, which caused the model to depart from reality with

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[36] *See, e.g.,* **JA**476, **JA**517, **JA**574, **JA**626, **JA**482, **JA**523, **JA**581, **JA**630.

[37] In the district court, HHS advanced the *post hoc* argument that charges fluctuate significantly and costs "tend to be more stable." **JA**198-99 (citing **JA**629). Therefore, HHS said, it was appropriate for its model to project charges on the basis of one year of recent data—apparently in order to capture fully the extent of the fluctuations—while using a complex multi-year model to smooth the stable cost data yet further. *Id.* This seems backwards. After all, if the goal was stable projections without large fluctuations, as the rulemakings said, one would think the more stable data set (costs) would need less manipulation, not more. HHS's new explanation would have been arbitrary and capricious if it had appeared in the rules. The fact that HHS developed it during the litigation, and could point to nothing better in the rulemaking records, shows just how thin the "more accurate and stable" justification was.

respect to several of its metrics. Yet HHS arbitrarily and capriciously continued to use the model without examining or addressing the issues identified by the commenters. *See PPL Wallingford Energy LLC*, 419 F.3d at 1198 (agency's failure to respond meaningfully to objections renders decision arbitrary and capricious).

Specifically, to substitute for the actual record data on the decline in charge ratios, HHS cobbled together trends and models of various other factors. HHS stated that these trends and modeled factors reflected contemporaneous cost and charge increases, but HHS was wrong in important ways. *See, e.g.*, **JA**476 (2008).

First, one of HHS's factors was the Medicare "market basket" rate-of-increase in costs, which HHS used to project average hospital cost inflation.[38] However, as commenters warned, this market basket increase did not have a consistent relationship to the average rate of hospital cost inflation. **JA**460 (noting "[i]t is not clear if the historical record supports the assumption that costs and the market basket maintain a relatively constant relationship over time" and pointing out substantial relative divergences). HHS acknowledged it had no particular reason to expect the market basket cost metric would track the costs HHS was trying to model. **JA**476 (2008) ("There are times where the market basket and

[38] The Medicare market basket is an index that measures the inflation in goods and services used by hospitals in providing inpatient care. *See, e.g.,* **JA**473.

the cost per discharge will be constant, while other times these values will differ from each other, depending on the fiscal year."). Yet HHS never addressed the issue raised by the comment or otherwise confronted this defect in its model, despite asserting its model was somehow more stable than the actual record data. *See, e.g., Bus. Roundtable*, 647 F.3d at 1151 (agency had "not sufficiently supported its conclusion," especially in light of the empirical evidence that plaintiffs brought to its attention).

Additional metrics further revealed how far off HHS's method was. The model's two key outputs (an estimate of cost inflation and an estimate of the rate of decline in charge ratios) were repeatedly wrong. For example, whereas the actual data for HHS's 2008 calculation shows a three-year trend of steady decline in the rate of cost inflation (from 7.15%, to 6.17%, then to 5.64%), HHS modeled that cost inflation would increase to 6.49%. **JA**476. That data used for 2008 also revealed that, the previous year, HHS's model had over-estimated cost inflation by almost 33%.[39] When HHS used the model for 2009, the record showed that HHS's 2008 calculation had again significantly over-estimated cost inflation (this time by

[39] For 2007, HHS's model had produced a projected one-year cost inflation statistic of 7.6%, but HHS's actual data used for 2008 showed cost inflation for the same period of had been only 5.64%. *Compare* **JA**476 (2008), *with* 71 Fed. Reg. at 48,150 (2007). And while these differences might seem somewhat small in the abstract, the 30% overestimate of cost inflation in 2007 significantly reduced the adjustment factor, which contributed towards an underpayment in excess of $400 million.

almost 20%).[40] And the ultimate output of HHS's model, an artificial rate of decline in charge ratios, was *less* accurate and/or stable year-to-year than the actual historical trend. *See* table *supra* at 30. For example, HHS's 2008 rulemaking showed that its 2007 threshold, which had used the artificial rate of decline, had significantly underpaid, **JA**478,[41] and that the actual historical decline in charge ratios had been seven times larger than what HHS had modeled the previous year. *See* **JA**460. Nonetheless HHS persisted with the same faulty model without addressing its failed results, thereby producing adjustment factors that did not even approximate the actual record trend.[42]

A second major defect in HHS's adjustment-factor model was that it combined data from different time periods. The actual record charge ratios were determined using cost and charge data from the same time period. However, HHS modeled cost increases from an earlier period to be divided by historical charge increases from a later period. Given the divergence between the rates of growth of

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[40] *Compare* **JA**517 (2009) (computing actual 5.5% cost inflation through 2006), *with* **JA**476 (2008) (modeling 6.49% cost inflation through 2006).

[41] The Federation commented that HHS had paid only 4.6%, which represented approximately $420,000,000 of underpayment. **JA**446. In the final rule, HHS agreed that it had only paid 4.65%, so this fact was before the agency during the 2008 rulemaking. **JA**478.

[42]Indeed, in the 2010 rulemaking, a commenter expressly demonstrated that simply using the historical trend would generate more reliable forecasts. **JA**538, **JA**557. HHS did not respond to that observation beyond noting it. **JA**573-74.

costs and charges (charges increasing faster than costs)—a fact that HHS noted repeatedly in these and other rulemakings, and that motivated important decisions in its overall analysis[43]—combining cost and charge data from different times was an obvious error. This modeled error resulted in a much smaller downward adjustment factor than was clearly reflected in the actual record data.

In summary, HHS's formula for projecting the anticipated decline in charge ratios was irrational when judged against every relevant measure, including the most recent actual record data (which HHS used for other purposes in the same rule-making) showing the true decline in charge ratios nationally, the superior alternative suggested by commenters, and the failed results the model repeatedly produced. HHS's indifference to these failures and to the likelihood that its model would produce underpayments was arbitrary and capricious.

3. HHS unreasonably disregarded the impact of reconciliation when setting the threshold

In its 2003 rulemaking, HHS stated that "the payment system remains vulnerable to overpayments," even after the rule changed the overall payment scheme; and that "reconciliation is necessary to ensure that outlier payments are appropriately paid in the future." **JA**327-28. Reconciliation would mean

[43] 69 Fed. Reg. at 49,277 (2005); 70 Fed. Reg. 23,306, 23,469 (proposed May 4, 2005) (2006); 71 Fed. Reg. at 24,150 (2007); 71 Fed. Reg. at 48,149 (2007); **JA**435 (2008); **JA**477 (2008); **JA**485 (2009); **JA**518 (2009).

that HHS recouped some amount of payments previously made, so that actual outlier payments would be below their initial, apparent total. Thus, a payment forecast that failed to account for reconciled payments would overstate the amount hospitals would actually receive—an important error that could significantly affect threshold-setting. Nonetheless, when setting each of its 2008-2011 thresholds, HHS uniformly refused to account for reconciliation.

HHS offered two principal reasons and each was arbitrary and capricious. First, HHS asserted there was no need to model reconciliation given the 2003 amendments to the payment regulation. **JA**186; **JA**477 (2008); **JA**518 (2009); **JA**574-75 (2010); **JA**626 (2011). This rationalization represented an about-face from what HHS said when it adopted those 2003 amendments: *viz.*, that reconciliation was necessary *despite* the amendments, because the amendments would not eliminate overcharging. In the 2010 rule, HHS's position was inconsistent within the rule itself; in a separate portion HHS said charges had fluctuated "over much of the last decade" because "even after the outlier policy was adopted, we continued to see evidence of these charge practices in the data." **JA**629; *see also* **JA**198 (citing this rule's observation on charge fluctuations to justify HHS's different treatment of charge and cost data). HHS did not explain these changes in position; HHS simply asserted that the 2003 amendments had eliminated overcharging and did not acknowledge that in the

2003 amendments it had a different view. HHS's willingness to adopt whatever rationale served the moment, regardless of its prior policies, was capricious.[44] *See, e.g., FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2008) (holding an agency must provide a "detailed justification" when "its new policy rests upon factual findings that contradict those which underlay its prior policy").

Moreover, HHS's own data demonstrated that, on average, more than 50 hospitals a year were referred for reconciliation. *See* Daniel Levinson, Dep't of Health & Human Servs., Inspector General, *[HHS] Did Not Reconcile Medicare Outlier Payments in Accordance with Federal Regulations and Guidance* (A-07-10-02764) (June 28, 2012), at ii, 9 ("OIG Report").[45] *See also* **JA**216-17 (acknowledging approximately 50 hospitals were reconciled on average each year).[46] In the district court, HHS argued that reconciliation of only 50 providers could not materially affect the calculation of the threshold. **JA**216-17. Besides being *post hoc* argument of counsel rather than the reasoning expressed by

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[44] Even though HHS did not publicly disclose the number of outlier reconciliation referrals, commenters requested that the agency take reconciliation into account in 2010-2011. **JA**541-42, **JA**599-00.

[45] Available at https://oig.hhs.gov/oas/reports/region7/71002764.pdf.

[46] Below, HHS attempted to avoid the findings of the OIG Report by arguing that the report postdates the rulemakings. **JA**186-87. However, HHS has not denied that basic hospital data such as referral for reconciliation were part of the files that HHS analyzed during the rulemaking. And HHS has already conceded that the district court could take judicial notice of the OIG Report. **JA**187.

the agency during the rulemakings,[47] this suggestion also represents an unexplained departure from HHS's past practice. In 2003 HHS overhauled the outlier regulations due to only about twice as many turbo-charging hospitals, *see* **JA**310, and in the 2004 threshold rulemaking HHS considered the reconciliation of about 50 hospitals to be critical to the analysis, 68 Fed. Reg. at 45,476-77. It is easy to see why it would be. Reconciliation was intended for hospitals that "disproportionately benefited" from vulnerabilities in the payment regulation, **JA**328, so the 50 hospitals would likely be among the largest recipients.[48] HHS has not—in its rulemakings or in its briefs thus far in this case—explained why it departed from its prior practice and ignored reconciliation for the years here at issue. *Fox TV Stations, Inc.*, 556 U.S. at 515; *State Farm*, 463 U.S. at 43 (requiring an agency to "examine the relevant data and articulate a satisfactory explanation for its action").

Second, HHS asserted that it would be difficult to model reconciliation because it would be hard to predict which hospitals would actually be reconciled. However, if a number is important—as HHS's past practice showed this one was—the fact that estimating may be difficult is not a rational excuse for ignoring it

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[47] *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 803 (D.C. Cir. 1984).

[48] Indeed, the OIG Report reveals that approximately $650,000,000 in potential outlier overpayments were referred to HHS just from 2004-2009.

entirely. *See Chamber of Commerce v. SEC*, 412 F.3d 133, 143 (D.C. Cir. 2005) (difficulty in modeling the effects of reconciliation did not excuse HHS from its "obligation to determine as best it can the … implications of the rule it has proposed"). HHS was obligated to make an effort to estimate the amount of reconciliation, even if the estimate was rough. Besides, HHS's justification is not logical. To account for reconciliation in setting the threshold, what mattered was the total amount of reconciled payments, not the identities of the hospitals with payments at issue. That it was difficult to say *which* hospitals might undergo reconciliation does not imply that HHS could not estimate their impact.

Last, HHS asserted in the rulemakings that the impact of reconciliation would be trivial and therefore need not be modeled.[49] This assertion, however, was contradicted by the substantial volumes of payments subject to reconciliation, as revealed by the OIG Report.

An agency acts unreasonably when it fails to consider evidence that may undermine its assumptions. *See, e.g., AEP Texas N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 443 (D.C. Cir. 2010) (holding that an agency acted arbitrarily in not considering evidence that contradicted its methodology to calculate a transportation-service rate); *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1515 (D.C. Cir. 1984) (same with respect to rate-making methodology

[49] *See* 69 Fed. Reg. at 49,278 (2005), **JA**477 (2008), **JA**518 (2009).

applied to oil pipelines). Here, HHS erred when it categorically assumed that any "amount of money recovered through reconciliation was not relevant." **JA**205-06.[50]

## C. HHS's 2003 Rulemaking Violated The APA's Notice And Comment Requirements Under 5 U.S.C. § 553

HHS has for years been indifferent to its obligation to set thresholds that are likely to provide adequate compensation for outlier cases. But the methodological flaws described above can be traced most directly to the 2003 rulemaking, in which HHS revised its outlier payment regulations. There, HHS recognized that its regulations facilitated turbo-charging, a practice that had led HHS to make billions of dollars of unauthorized payments to hospitals that manipulated the system. But HHS ignored the fact that its payment system had also underpaid the legitimate claims of all other hospitals. HHS could have fixed that aspect of the program as well, by correcting methodological problems like those described above. Had it done so, HHS would have had a sound threshold-setting process in place prior to the 2008-2011 determinations.[51]

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[50] Below, HHS also asserted that it was not legally obligated to reconcile outlier payments. **JA**205-06. Not only is this explanation irrelevant because it is *post hoc*, *see supra* note 47, it is also beside the point. Regardless of whether HHS was legally obligated to conduct reconciliation, it needed to account for the amount of unlawful payments that it reasonably expected to recoup through the process.

[51] HHS argued that the district court lacked jurisdiction over challenges to the 2003 rulemaking, on the ground that they were not among the issues on which the

That HHS could have solved these problems in the 2003 rulemaking is not merely theoretical. HHS had prepared a draft Interim Final Rule which implemented a threshold-setting methodology much like what commenters have suggested and this brief has advocated. That methodology accounted for the effect of declining charge ratios by using a simple average of recent historical changes to project charge ratios forward in time. **JA**405-06. It also identified turbo-charging hospitals (which, in 2008-2011, would have been prospects for reconciliation) and accounted for such invalid payments accordingly. **JA**403-04. The result of those methodological changes was a determination that a threshold of about $20,000, rather than above $33,000, was necessary to make it likely that outlier payments would be at the 5.1% target. **JA**376, **JA**406.

HHS drew extensively on that analysis in its 2003 notice of proposed rulemaking (NPRM) to amend the outlier payment regulations. HHS admitted to this Court, that the draft Interim Final Rule was the source of much of the contents of that proposal. *See* Initial Brief for the Appellee at 80, *Banner Health* (Feb. 6, 2017) (conceding that "other aspects of the [Interim Final Rule] ended up becoming part of HHS's proposed rulemaking"). But, in the 2003 NPRM, HHS

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review board granted expedited review. The district court held, the Hospitals believe correctly, that the board's grant of review was broad and encompassed all of the Hospitals' challenges to the validity of the 2003 regulation. *See* **JA**279 ("The [board] certified this entire question.").

presented the analysis selectively. For example, while HHS described how turbo-charging had affected thresholds, **JA**310, it omitted—and never presented to the public—the detailed analysis (summarized *supra* at 7-8) that concluded the threshold should immediately be lowered from $33,560 to $20,760. **JA**401-06.

HHS's failure to provide public notice of the full contents of the draft Interim Final Rule deprived the Hospitals of an opportunity to comment on important material germane to the question of how HHS would determine thresholds.[52] Under 5 U.S.C. § 553, an agency may not selectively disclose only those portions of an analysis or study that support its rulemaking but exclude adverse portions that contradict its rulemaking. *Am. Radio Relay League v. FCC*, 524 F.3d 227, 237-39 (D.C. Cir. 2008) ("*American Radio*"). In *American Radio*, the FCC relied on certain technical studies, but had redacted portions of those studies adverse to its rulemaking. *Id.* Despite the FCC's assertion that it could hide the redacted portions because they "were not relied upon," the Court found that a commenter may have had "something useful to say regarding the unredacted studies, that [might have] allow[ed] it to mount a credible challenge…." *Id.* at 237-38 (internal quotation marks omitted). Similarly here, HHS's 2003

[52] As one commenter highlighted in 2003, "[t]he absence of any quantitative data … regarding the effects of the proposed payment changes ... makes it very difficult for us ... to provide ... meaningful comment…. These data are absolutely critical to assessing the impact of the proposed regulation." **JA**317-18.

rulemaking relied extensively on the draft Interim Final Rule, but disclosed only an effectively redacted version of the complete study and analysis therein set forth.

Had HHS provided the public an adequate opportunity to comment on the 2003 rule, the Hospitals (as well as other commenters) would have provided sound reasons to adopt—and use for all subsequent threshold determinations, including 2008- 2011—the methodological changes set forth in the draft Interim Final Rule. Accordingly, this Court should vacate the 2003 rulemaking with respect to the determination of threshold and remand to HHS to provide proper notice and comment prior to reissuing the rule.[53]

## VIII. CONCLUSION

The Hospitals respectfully request that the Court (1) declare HHS's rulemakings setting the 2008-2011 thresholds as arbitrary, capricious, an abuse of discretion, contrary to the statutory mandate, and/or otherwise substantively not in accordance with law; (2) declare HHS's rulemaking setting the 2003 payment regulations to be in violation of the APA's notice and comment requirements; (3) vacate the 2008-2011 thresholds, and remand to HHS to recalculate the 2008-2011 thresholds; (4) vacate the portion of the 2003 rulemaking maintaining the 2003

[53] A similar challenge to the procedural validity of the 2003 rulemaking is pending decision by this Court in *Banner Health*.

threshold and remand to HHS to provide proper notice and comment prior to reissuing the rule; and (5) grant such other and further relief as may be in accordance with this Court's rulings.

## CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

1. This brief complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the brief exempted by Fed. R. App. 32(f), this brief contains 10,675 words.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman.

Dated: October 20, 2017

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## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on this 20th day of October, 2017 I served the foregoing *Final Brief for the Appellants* electronically via the Court's CM/ECF System upon the following counsel of record for Appellee:


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